

## We Claim:

1. A drug delivery regimen, which comprises:  
an active therapeutic substance(s) selected from the  
group consisting of anti-hypertensive agents,  
osteoporotic agents, GERD agents, anti-viral agents,  
anti-neoplastic agents, inhaled steroids, lipid lowering  
agents, thrombolytic agents, anticoagulant agents,  
fibrinolytic agents, anti-asthmatics, hormone replacement  
agents, anti-infectives, anti-diabetics, vitamins, herbal  
agents, minerals, fatty acids, electrolytes and  
combinations thereof administered multiple times during  
at least one 24 hour period of time to provide effective  
therapeutic levels of the active therapeutic substance(s)  
at a site or sites of action in an animal over said  
period, wherein each individual dose is independently  
adjusted to be administered to optimize levels of the  
active therapeutic substance(s) at the site or sites of  
action for maximum efficacy, and wherein the dose amount  
at each administration is independently characterized by  
the formula  $TD(t) = CD(t) + RD(t)$ , where  $t$  is the time at  
which the dose is to be administered,  $TD$  (therapeutic  
dose) is the therapeutically effective dose at time ( $t$ ),  
 $CD$  (current dose) is the dose to be administered at time

(t), and RD (residual dose) is the amount of active therapeutic substance(s) remaining from the previous dose administration.

5           2. The drug delivery regimen of claim 1, wherein  
the drug delivery regimen agent is selected from the  
group consisting of calcium channel blockers, ACE  
inhibitors, angiotensin II receptor antagonists, beta-  
adrenoceptor antagonists, alpha 1-adrenoceptor  
10 antagonists, alpha 2-adrenoceptor antagonists, diuretics  
and combinations thereof.

          3. The drug delivery regimen of claim 2, wherein  
the calcium channel blocker is nifedipine, verapamil,  
15 nifedipine, diltiazem, isradipine, amlodipine,  
felodipine, nifedipine, bepridil and combinations  
thereof.

          4. The drug delivery regimen of claim 2, wherein  
20 the ACE inhibitor is quinapril, ramipril, captopril,  
benazepril, fosinopril, lisinopril, moexipril, enalapril  
and combinations thereof.

5. The drug delivery regimen of claim 2, wherein the angiotensin II receptor antagonist is losartan.

6. The drug delivery regimen of claim 2, wherein the beta adrenoceptor antagonist is sotalol, timolol, esmolol, carteolol, propanolol, betaxolol, penbutolol, metoprolol, labetalol, acebutolol, atenolol, bisoprolol and combinations thereof.

7. The drug delivery regimen of claim 2, wherein the alpha 1-adrenoceptor antagonist is doxazosin, phenoxybenzamine, guanethidine, guanadrel, terazosin, prazosin and combinations thereof.

8. The drug delivery regimen of claim 2, wherein the alpha 2-adrenoceptor agonist is methyldopa, clonidine, guanfacine and combinations thereof.

9. The drug delivery regimen of claim 2, wherein the diuretic is selected from the group consisting of carbonic anhydrase inhibitors, loop diuretics, thiazides, potassium sparing diuretics and combinations thereof.

10. The drug delivery regimen of claim 1, wherein the osteoporotic agent is alendronate, etidronate, pamidronate, clodronate, tiludronate, residronate, ibandronate and combinations thereof.

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11. The drug delivery regimen of claim 1, wherein the GERD agent is oral GI prokinetic agents, agents active against *H. Pylori*, proton pump inhibitors, H<sub>2</sub> histamine receptor antagonists, antacids and combinations thereof.

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12. The drug delivery regimen of claim 11, wherein the oral GI prokinetic agent is cisapride monohydrate, metoclopramide and combinations thereof.

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13. The drug delivery regimen of claim 11, wherein the agent active against *H. Pylori* is clarithromycin, tetracycline, amoxicillin, bismuth, metronidazole and combinations thereof.

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14. The drug delivery regimen of claim 11, wherein the proton pump inhibitor is omeprazole, lansoprazole and combinations thereof.

15. The drug delivery regimen of claim 11, wherein the H<sub>2</sub> histamine receptor antagonist is cimetadine, famotidine, nizatidine, ranitidine, roxatidine and combinations thereof.

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16. The drug delivery regimen of claim 1, wherein the anti-viral agent is nucleoside analogs, protease inhibitors and combinations thereof.

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17. The drug delivery regimen of claim 16, wherein the nucleoside analog is zidovudine, azidothymidine, didanosine, zalcitabine, stavudine, lamivudine and combinations thereof.

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18. The drug delivery regimen of claim 16, wherein the protease inhibitor is saquinavir mesylate, ritonavir, indinavir and combinations thereof.

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19. The drug delivery regimen of claim 1, wherein the anti-neoplastic agent is selected from the group consisting of cytotoxic agents, anti-metabolites, platinum-containing compounds, antibiotic derivatives, fluoropyrimidines, nitrosoureas, vinca alkaloids,

nitrogen mustard derivatives, adjuvant biological response modifiers and combinations thereof.

20. The drug delivery regimen of claim 19, wherein  
5 the cytotoxic agent is paclitaxel, cyclophosphamide, teniposide and combinations thereof.

21. The drug delivery regimen of claim 19, wherein  
the anti-metabolite is methotrexate.

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22. The drug delivery regimen of claim 19, wherein  
the platinum-containing compound is cisplatin (cis-diaminedichlororoplatinum), carboplatin, oxaliplatin and combinations thereof.

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23. The drug delivery regimen of claim 19, wherein  
the antibiotic derivative is adriamycin, bleomycin, dactinomycin, daunorubicin, doxorubicin, indarubicin, mytomicin and combinations thereof.

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24. The drug delivery regimen of claim 19, wherein  
the fluoropyrimidine is 5-FU (5-fluorouracil), FudR (5-

fluoro-2'-deoxyuridine), Ara-C (arabinosylcytosine) and combinations thereof.

25. The drug delivery regimen of claim 19, wherein  
5 the nitrosourea is BCNU (carmustine), streptozocin and combinations thereof.

26. The drug delivery regimen of claim 19, wherein  
10 the vinca alkaloid is vinblastine, vincristine and combinations thereof.

27. The drug delivery regimen of claim 19, wherein the nitrogen mustard derivative is thiotepa.

15 28. The drug delivery regimen of claim 19, wherein the adjuvant biological response modifier is selected from the group consisting of alpha-interferon, TNF (tumor necrosis factor), EPO (erythropoietin), rhG-CSF (recombinant human granulocyte colony-stimulating  
20 factor), IL-1 (interleukin-1), IL-2 (interleukin-2), monoclonal antibodies to tumor and immunologic targets and combinations thereof.

29. The drug delivery regimen of claim 1, wherein  
the inhaled steroid is beclomethasone dipropionate,  
budesonide, flunisolide, fluticasone propionate,  
mometasone furoate, triamcinolone acetonide and  
5 combinations thereof.

30. The drug delivery regimen of claim 1, wherein  
the lipid lowering agent is nicotinic acid, HMG CoA  
reductase inhibitors, bile sequestration agents, fibric  
10 acid derivatives and combinations thereof.

31. The drug delivery regimen of claim 30, wherein  
the HMG CoA reductase inhibitor is atorvastatin,  
cerivastatin, fluvastatin, lovastatin, pravastatin,  
15 simvastatin and combinations thereof.

32. The drug delivery regimen of claim 30, wherein  
the bile sequestration agent is colestipol,  
cholestyramine and combinations thereof.

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33. The drug delivery regimen of claim 30, wherein  
the fibric acid derivative is clofibrate, gemfibrozil and  
combinations thereof.

34. The drug delivery regimen of claim 1, wherein the thrombolytic, anticoagulant, fibrinolytic agent is selected from the group consisting of heparin-like agents, clot buster agents, aspirin-like agents, platelet glycoprotein IIb, IIIa receptor antagonists and combinations thereof.

35. The drug delivery regimen of claim 34, wherein the heparin-like agent is selected from the group consisting of enoxaparin, dalteparin, refludan and combinations thereof.

36. The drug delivery regimen of claim 34, wherein the clot buster agent is streptokinases, alteplase (TPA) and combinations thereof.

37. The drug delivery regimen of claim 34, wherein the aspirin-like agent is a thromboxane inhibitor.

38. The drug delivery regimen of claim 34, wherein the platelet glycoprotein IIb, IIIa receptor antagonist is tirofiban, eptifibatide, abciximab and combinations thereof.

39. The drug delivery regimen of claim 1, wherein  
the vitamin thiamine, niacinamide, pyridoxine, ascorbic  
acid, riboflavin, folic acid, vitamin A, vitamin E,  
vitamin D3, cyanocobalamin, biotin, pantothenic acid,  
5 derivatives thereof, and combinations thereof.

40. The drug delivery regimen of claim 1, wherein  
the herbal agent is black cohosh, licorice, false  
unicorn, siberian ginseng, sarsaparilla, squaw vine,  
10 blessed thistle, peppermint, spearmint, red raspberry,  
St. Johnswort, ginger, kola, hops, valerian, derivatives  
thereof and combinations thereof.

41. The drug delivery regimen of claim 1, wherein  
15 the fatty acid is selected from the group consisting of  
linoleic acid, linolenic acid, docosahexaenoic acid,  
arachidonic acid, eicosahexaenoic acid, omega-3 fatty  
acid, omega-2 fatty acid, derivatives thereof and  
combinations thereof.

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42. The drug delivery regimen of claim 1, wherein  
the mineral is selected from the group consisting of  
copper, zinc, iodide, magnesium, chromium, molybdenum,

sodium, calcium, iron, fluoride, phosphorus, manganese, potassium, boron, selenium, bioflavonoid, phosphate, derivatives thereof and combinations thereof.

5           43. The drug delivery regimen of claim 1, wherein  
the electrolyte is selected from the group consisting of  
potassium, magnesium, sodium, calcium, derivatives  
thereof and combinations thereof.

10           44. The drug delivery regimen of claim 1, wherein  
the active therapeutic substance(s) is administered to  
increase efficacy.

15           45. The drug delivery regimen of claim 1, wherein  
the active therapeutic substance(s) is administered to  
reduce the total dosage administered per day while  
maintaining equivalent efficacy.

20           46. The drug delivery regimen of claim 1, wherein  
the active therapeutic substance(s) is administered to  
minimize incidents of side effects.

47. The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered to improve patient compliance with the drug delivery regimen.

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48. The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered to improve convenience of administration.

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49. The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered at least once and may be administered as immediate release, sustained release, controlled release, delayed release, timed release, extended release, or any combination thereof.

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50. The drug delivery regimen of claim 5, wherein the active therapeutic substance(s) is administered by pulsatile delivery of the active therapeutic substance(s).

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51. The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered in

one or more dosage forms independently selected from the group consisting of chewable tablets, quick dissolve tablets, effervescent tablets, reconstitutable powders, elixirs, liquids, solutions, suspensions, emulsions, tablets, multi-layer tablets, bi-layer tablets, capsules, soft gelatin capsules, hard gelatin capsules, caplets, lozenges, chewable lozenges, beads, powders, granules, particles, microparticles, dispersible granules, cachets, douches, suppositories, creams, topicals, inhalants, aerosol inhalants, patches, particle inhalants, implants, depot implants, ingestibles, injectables, infusions, health bars, confections, animal feeds, cereals, cereal coatings, foods, nutritive foods, functional foods, by a vaporizer and combinations thereof.

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52. The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered in two or more dosage forms independently selected from the group consisting of tablet, multi-layer tablet, capsule, or caplet.

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53. The drug delivery regimen of claim 52, wherein the multi-layer tablet is composed of an extended-release layer and an immediate release layer.

5 54. The drug delivery regimen of claim 52, wherein the dosage form is coated for ease of administration, coated for delayed release or enteric coated to reduce gastric irritation.

10 55. The drug delivery regimen of claim 52, wherein the dosage form is enteric coated and compressed into a tablet or filled into hard or soft gelatin capsules.

15 56. The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered in uneven doses.

20 57. The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is administered at uneven time intervals over the course of the 24 hour period.

58. The drug delivery regimen of claim 1, wherein an AM dose and a PM dose are administered, and wherein the AM dose is larger or smaller than the PM dose.

5 59. The drug delivery regimen of claim 1, wherein an AM dose and a PM dose are administered, and wherein the AM dose has a higher or lower amount of a water-soluble active therapeutic substance(s) present than that present in the PM dose.

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60. The drug delivery regimen of claim 1, wherein an AM dose and a PM dose are administered, and wherein the AM dosage has a higher or lower amount of a non water-soluble drug present than that present in the PM dosage.

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61. The drug delivery regimen of claim 1, wherein the dosage is adjusted for subsequent 24 hour periods of time.

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62. The drug delivery regimen of claim 1, wherein the active therapeutic substance(s) is substituted for another active therapeutic substance(s).

63. The drug delivery regimen of claim 1, wherein two PM doses are administered, and wherein the first PM dose is administered immediately after dinner and the second PM dose is administered immediately prior to bedtime.

64. A drug delivery regimen, which comprises:  
at least two dose of an active therapeutic substance(s) selected from the group consisting of an anti-hypertensive agent, an osteoporotic agent, a GERD agent, an anti-viral agent, an anti-neoplastic agent, an inhaled steroid, a lipid lowering agent, a thrombolytic agent, an anticoagulant agent, a fibrinolytic agent, a vitamin, an herbal agent, a mineral, a fatty acid, an electrolyte and combinations thereof administered during at least one 24 hour period of time to provide effective therapeutic levels of the active therapeutic substance(s) at a site or sites of action in an animal over said period, wherein the active therapeutic substance(s) is administered in uneven doses and over varying time intervals, and wherein the uneven doses and the varying time intervals are selected to optimize levels of the active therapeutic

substance(s) at the site or sites of action for maximum efficacy.

65. The drug delivery regimen of claim 64, wherein  
5 the anti-hypertensive agent is selected from the group  
consisting of a calcium channel blocker, an ACE  
inhibitor, an angiotensin II receptor antagonist, a beta-  
adrenoceptor antagonist, an alpha 1-adrenoceptor  
antagonists, an alpha 2-adrenoceptor antagonist, a  
10 diuretic and combinations thereof.

66. The drug delivery regimen of claim 65 wherein  
the calcium channel blocker is selected from the group  
consisting of nifedipine, verapamil, nicardipine,  
15 diltiazem, isradipine, amlodipine, felodipine,  
nifedipine, bepridil and combinations thereof.

67. The drug delivery regimen of claim 65, wherein  
the ACE inhibitor is selected from the group consisting  
20 of quinapril, ramipril, captopril, benazepril,  
fosinopril, lisinopril, moexipril, enalapril and  
combinations thereof.

68. The drug delivery regimen of claim 65 wherein the angiotensin II receptor antagonist is losartan.

69. The drug delivery regimen of claim 65, wherein the beta adrenoceptor antagonist is selected from the group consisting of sotalol, timolol, esmolol, carteolol, propanolol, betaxolol, penbutolol, metoprolol, labetalol, acebutolol, atenolol, bisoprolol and combinations thereof.

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70. The drug delivery regimen of claim 65, wherein the alpha 1-adrenoceptor antagonist is selected from the group consisting of doxazosin, phenoxybenzamine, guanethidine, guanadrel, terazosin, prazosin and combinations thereof.

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71. The drug delivery regimen of claim 65, wherein the alpha 2-adrenoceptor agonist is selected from the group consisting of methyldopa, clonidine, guanfacine and combinations thereof.

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72. The drug delivery regimen of claim 65, wherein the diuretic is selected from the group consisting of

carbonic anhydrase inhibitors, loop diuretics, thiazides, potassium sparing diuretics and combinations thereof.

5           73. The drug delivery regimen of claim 64, wherein the osteoporotic agent is selected from the group consisting of alendronate, etidronate, pamidronate, clodronate, tiludronate, residronate, ibandronate and combinations thereof.

10           74. The drug delivery regimen of claim 64, wherein the GERD agent is selected from the group consisting of oral GI prokinetic agents, agents active against *H. Pylori*, proton pump inhibitors, H<sub>2</sub> histamine receptor antagonists, antacids and combinations thereof.

15           75. The drug delivery regimen of claim 74, wherein the oral GI prokinetic agent is selected from the group consisting of cisapride monohydrate, metoclopramide and combinations thereof.

20           76. The drug delivery regimen of claim 74, wherein the agent active against *H. Pylori* is selected from the group consisting of clarithromycin, tetracycline,

amoxicillin, bismuth, metronidazole and combinations thereof.

77. The drug delivery regimen of claim 74, wherein  
5 the proton pump inhibitor is selected from the group  
consisting of omeprazole, lansoprazole and combinations  
thereof.

78. The drug delivery regimen of claim 74, wherein  
10 the H<sub>2</sub> histamine receptor antagonist is selected from the  
group consisting of cimetadine, famotidine, nizatidine,  
ranitidine, roxatidine and combinations thereof.

79. The drug delivery regimen of claim 64, wherein  
15 the anti-viral agent is selected from the group  
consisting of nucleoside analogs, protease inhibitors and  
combinations thereof.

80. The drug delivery regimen of claim 79, wherein  
20 the nucleoside analog is selected from the group  
consisting of zidovudine, azidothymidine, didanosine,  
zalcitabine, stavudine, lamivudine and combinations  
thereof.

81. The drug delivery regimen of claim 79, wherein the protease inhibitor is selected from the group consisting of saquinavir mesylate, ritonavir, indinavir and combinations thereof.

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82. The drug delivery regimen of claim 64, wherein the anti-neoplastic agent is selected from the group consisting of cytotoxic agents, anti-metabolites, platinum-containing compounds, antibiotic derivatives, fluoropyrimidines, nitrosoureas, vinca alkaloids, nitrogen mustard derivatives, adjuvant biological response modifiers and combinations thereof.

83. The drug delivery regimen of claim 82, wherein the cytotoxic agent is selected from the group consisting of paclitaxel, cyclophosphamide, teniposide and combinations thereof.

84. The drug delivery regimen of claim 82, wherein the anti-metabolite is methotrexate.

85. The drug delivery regimen of claim 82, wherein the platinum-containing compound is selected from the

group consisting of cisplatin (cis-diaminedichlororoplatinum), carboplatin, oxaliplatin and combinations thereof.

5           86. The drug delivery regimen of claim 82, wherein the antibiotic derivative is selected from the group consisting of adriamycin, bleomycin, dactinomycin, daunorubicin, doxorubicin, indarubicin, mytomycin and combinations thereof.

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          87. The drug delivery regimen of claim 82, wherein the fluoropyrimidine is selected from the group consisting of 5-FU (5-fluorouracil), FudR (5-fluoro-2'-deoxyuridine), Ara-C (arabinosylcytosine) and  
15 combinations thereof.

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          88. The drug delivery regimen of claim 82, wherein the nitrosourea is selected from the group consisting of BCNU (carmustine), streptozocin and combinations thereof.

          89. The drug delivery regimen of claim 82, wherein the vinca alkaloid is selected from the group consisting of vinblastine, vincristine and combinations thereof.

90. The drug delivery regimen of claim 82, wherein the nitrogen mustard derivative is thiotepa.

91. The drug delivery regimen of claim 82, wherein  
5 the adjuvant biological response modifier is selected from the group consisting of alpha-interferon, TNF (tumor necrosis factor), EPO (erythropoietin), rhG-CSF (recombinant human granulocyte colony-stimulating factor), IL-1 (interleukin-1), IL-2 (interleukin-2),  
10 monoclonal antibodies to tumor and immunologic targets and combinations thereof.

92. The drug delivery regimen of claim 64, wherein the inhaled steroid is selected from the group consisting  
15 of beclomethasone dipropionate, budesonide, flunisolide, fluticasone propionate, mometasone furoate, triamcinolone acetonide and combinations thereof.

93. The drug delivery regimen of claim 64, wherein  
20 the lipid lowering agent is selected from the group consisting of nicotinic acid, HMG CoA reductase inhibitors, bile sequestration agents, fibric acid derivatives and combinations thereof.

94. The drug delivery regimen of claim 93, wherein the HMG CoA reductase inhibitor is selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, pravastatin, simvastatin and combinations thereof.

95. The drug delivery regimen of claim 93, wherein the bile sequestration agent is selected from the group consisting of colestipol, cholestyramine and combinations thereof.

96. The drug delivery regimen of claim 93, wherein the fibric acid derivative is selected from the group consisting of clofibrate, gemfibrozil and combinations thereof.

97. The drug delivery regimen of claim 64, wherein the thrombolytic, anticoagulant, fibrinolytic agent is selected from the group consisting of heparin-like agents, clot buster agents, aspirin-like agents, platelet glycoprotein IIb, IIIa receptor antagonists and combinations thereof.

98. The drug delivery regimen of claim 97, wherein the heparin-like agent is selected from the group consisting of enoxaparin, dalteparin, refludan and combinations thereof.

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99. The drug delivery regimen of claim 97, wherein the clot buster agent is selected from the group consisting of streptokinases, alteplase (TPA) and combinations thereof.

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100. The drug delivery regimen of claim 97, wherein the aspirin-like agent is a thromboxane inhibitor.

101. The drug delivery regimen of claim 97, wherein the platelet glycoprotein IIb, IIIa receptor antagonist is selected from the group consisting of tirofiban, eptifibatide, abciximab and combinations thereof.

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102. The drug delivery regimen of claim 64, wherein the vitamin is selected from the group consisting of thiamine, niacinamide, pyridoxine, ascorbic acid, riboflavin, folic acid, vitamin A, vitamin E, vitamin D3,

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cyanocobalamin, biotin, pantothenic acid, derivatives thereof, and combinations thereof.

103. The drug delivery regimen of claim 64, wherein  
5 the herbal agent is selected from the group consisting of black cohosh, licorice, false unicorn, siberian ginseng, sarsaparilla, squaw vine, blessed thistle, peppermint, spearmint, red raspberry, St. Johnswort, ginger, kola, hops, valerian, derivatives thereof and combinations  
10 thereof.

104. The drug delivery regimen of claim 64, wherein  
the fatty acid is selected from the group consisting of linoleic acid, linolenic acid, docosaheaxanoic acid,  
15 arachidonic acid, eicosaheaxanoic acid, omega-3 fatty acid, omega-2 fatty acid, derivatives thereof and combinations thereof.

105. The drug delivery regimen of claim 64, wherein  
20 the mineral is selected from the group consisting of copper, zinc, iodide, magnesium, chromium, molybdenum, sodium, calcium, iron, fluoride, phosphorus, manganese,

potassium, boron, selenium, bioflavonoid, phosphate, derivatives thereof and combinations thereof.

106. The drug delivery regimen of claim 64, wherein  
5 the electrolyte is selected from the group consisting of potassium, magnesium, sodium, calcium, derivatives thereof and combinations thereof.

107. The drug delivery regimen of claim 64, wherein  
10 the active therapeutic substance(s) is administered at least once and may be administered as immediate release, sustained release, controlled release, delayed release, timed release, extended release, or any combination thereof.

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108. The drug delivery regimen of claim 107, wherein the active therapeutic substance(s) is administered by pulsatile delivery of the active therapeutic substance(s).

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109. The drug delivery regimen of claim 64, wherein the active therapeutic substance(s) is administered in a dosage form independently selected from the group

consisting of liquid, solution, suspension, emulsion, tablet, multi-layer tablet, capsule, soft gelatin capsule, caplet, lozenge, chewable lozenge, bead, powder, granules, dispersible granules, cachets, douche, suppository, cream, topical, inhalant, patch, particle inhalant, implant, ingestible, injectable, infusion health bar, confection, animal feed, cereal, cereal coating, food, nutritive food, functional food and combinations thereof.

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110. The drug delivery regimen of claim 64, wherein the active therapeutic substance(s) is administered in a dosage form independently selected from the group consisting of tablet, multi-layer tablet, capsule, or caplet.

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111. The drug delivery regimen of claim 110, wherein the multi-layer tablet is composed of an extended-release layer and an immediate release layer.

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112. The drug delivery regimen of claim 110, wherein the dosage form is coated for ease of

administration, coated for delayed release or enteric coated to reduce gastric irritation.

113. The drug delivery regimen of claim 110,  
5 wherein the dosage form is enteric coated and compressed into a tablet or filled into hard or soft gelatin capsules.

114. The drug delivery regimen of claim 64, wherein  
10 the active therapeutic substance(s) is administered in uneven doses.

115. The drug delivery regimen of claim 64, wherein  
15 the active therapeutic substance(s) is administered at uneven time intervals over the course of the 24 hour period.

116. The drug delivery regimen of claim 64, wherein  
20 an AM dose and a PM dose are administered, and wherein the AM dose is larger or smaller than the PM dose.

117. The drug delivery regimen of claim 64, wherein  
an AM dose and a PM dose are administered, and wherein

the AM dose has a higher or lower amount of a water-soluble active therapeutic substance(s) is present than that present in the PM dose.

5           118. The drug delivery regimen of claim 64, wherein an AM dose and a PM dose are administered, and wherein the AM dosage has a higher or lower amount of a non water-soluble drug present than that present in the PM dosage.

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119. The drug delivery regimen of claim 64, wherein the dosage is adjusted for subsequent 24 hour periods of time.

15           120. The drug delivery regimen of claim 64, wherein the active therapeutic substance(s) is substituted for another active therapeutic substance(s).

20           121. The drug delivery regimen of claim 64, wherein two PM doses are administered, and wherein the first PM dose is administered immediately after dinner and the second PM dose is administered immediately prior to bedtime.

122. A drug delivery regimen, which comprises:  
at least two doses of an active therapeutic substance(s)  
selected from the group consisting of an anti-  
hypertensive agent, an osteoporotic agent, a GERD agent,  
5 an anti-viral agent, an anti-neoplastic agent, an inhaled  
steroid, a lipid lowering agent, a thrombolytic agent, an  
anticoagulant agent, a fibrinolytic agent, an anti-  
asthmatic, a hormone replacement agent, an anti-  
infective, an anti-diabetic, a vitamin, an herbal agent,  
10 a fatty acid, a mineral, an electrolyte and combinations  
thereof is administered during at least one 24 hour  
period of time to provide effective therapeutic levels of  
the active therapeutic substance or substances at a site  
or sites of action in an animal over said period, and  
15 wherein each dose is independently calculated according  
to known pharmacokinetic parameters of the active  
therapeutic substance(s) with variations to account for  
physiological anomalies which occur during said period to  
optimize levels of the active therapeutic substance(s) at  
20 the site or sites of action for maximum efficacy.

123. The drug delivery regimen of claim 122,  
wherein the anti-hypertensive agent is selected from the

group consisting of a calcium channel blocker, an ACE inhibitor, an angiotensin II receptor antagonist, a beta-adrenoceptor antagonist, an alpha 1-adrenoceptor antagonists, an alpha 2-adrenoceptor antagonist, a  
5 diuretic and combinations thereof.

124. The drug delivery regimen of claim 123, wherein the calcium channel blocker is selected from the group consisting of nifedipine, verapamil, nicardipine,  
10 diltiazem, isradipine, amlodipine, felodipine, nifedipine, bepridil and combinations thereof.

125. The drug delivery regimen of claim 123, wherein the ACE inhibitor is selected from the group  
15 consisting of quinapril, ramipril, captopril, benazepril, fosinopril, lisinopril, moexipril, enalapril and combinations thereof.

126. The drug delivery regimen of claim 123,  
20 wherein the angiotensin II receptor antagonist is losartan.

127. The drug delivery regimen of claim 123, wherein the beta adrenoceptor antagonist is selected from the group consisting of sotalol, timolol, esmolol, carteolol, propanolol, betaxolol, penbutolol, metoprolol, labetalol, acebutolol, atenolol, bisoprolol and combinations thereof.

128. The drug delivery regimen of claim 123, wherein the alpha 1-adrenoceptor antagonist is selected from the group consisting of doxazosin, phenoxybenzamine, guanethidine, guanadrel, terazosin, prazosin and combinations thereof.

129. The drug delivery regimen of claim 123, wherein the alpha 2-adrenoceptor agonist is selected from the group consisting of methyldopa, clonidine, guanfacine and combinations thereof.

130. The drug delivery regimen of claim 123, wherein the diuretic is selected from the group consisting of carbonic anhydrase inhibitors, loop diuretics, thiazides, potassium sparing diuretics and combinations thereof.

131. The drug delivery regimen of claim 122, wherein the osteoporotic agent is selected from the group consisting of alendronate, etidronate, pamidronate, clodronate, tiludronate, residronate, ibandronate and combinations thereof.

132. The drug delivery regimen of claim 122, wherein the GERD agent is selected from the group consisting of oral GI prokinetic agents, agents active against *H. Pylori*, proton pump inhibitors, H<sub>2</sub> histamine receptor antagonists, antacids and combinations thereof.

133. The drug delivery regimen of claim 132, wherein the oral GI prokinetic agent is selected from the group consisting of cisapride monohydrate, metoclopramide and combinations thereof.

134. The drug delivery regimen of claim 132, wherein the agent active against *H. Pylori* is selected from the group consisting of clarithromycin, tetracycline, amoxicillin, bismuth, metronidazole and combinations thereof.

135. The drug delivery regimen of claim 132, wherein the proton pump inhibitor is selected from the group consisting of omeprazole, lansoprazole and combinations thereof.

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136. The drug delivery regimen of claim 132, wherein the H<sub>2</sub> histamine receptor antagonist is selected from the group consisting of cimetadine, famotidine, nizatidine, ranitidine, roxatidine and combinations thereof.

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137. The drug delivery regimen of claim 122, wherein the anti-viral agent is selected from the group consisting of nucleoside analogs, protease inhibitors and combinations thereof.

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138. The drug delivery regimen of claim 137, wherein the nucleoside analog is selected from the group consisting of zidovudine, azidothymidine, didanosine, zalcitabine, stavudine, lamivudine and combinations thereof.

20

139. The drug delivery regimen of claim 137, wherein the protease inhibitor is selected from the group consisting of saquinavir mesylate, ritonavir, indinavir and combinations thereof.

5

140. The drug delivery regimen of claim 122, wherein the anti-neoplastic agent is selected from the group consisting of cytotoxic agents, anti-metabolites, platinum-containing compounds, antibiotic derivatives, fluoropyrimidines, nitrosoureas, vinca alkaloids, nitrogen mustard derivatives, adjuvant biological response modifiers and combinations thereof.

10

141. The drug delivery regimen of claim 140, wherein the cytotoxic agent is selected from the group consisting of paclitaxel, cyclophosphamide, teniposide and combinations thereof.

15

142. The drug delivery regimen of claim 140, wherein the anti-metabolite is methotrexate.

20

143. The drug delivery regimen of claim 140, wherein the platinum-containing compound is selected from

the group consisting of cisplatin (cis-diaminedichlororoplatinum), carboplatin, oxaliplatin and combinations thereof.

5        144. The drug delivery regimen of claim 140, wherein the antibiotic derivative is selected from the group consisting of adriamycin, bleomycin, dactinomycin, daunorubicin, doxorubicin, indarubicin, mytomycin and combinations thereof.

10

145. The drug delivery regimen of claim 140, wherein the fluoropyrimidine is selected from the group consisting of 5-FU (5-fluorouracil), FudR (5-fluoro-2'-deoxyuridine), Ara-C (arabinosylcytosine) and combinations thereof.

15

146. The drug delivery regimen of claim 140, wherein the nitrosourea is selected from the group consisting of BCNU (carmustine), streptozocin and combinations thereof.

20

147. The drug delivery regimen of claim 140, wherein the vinca alkaloid is selected from the group

consisting of vinblastine, vincristine and combinations thereof.

148. The drug delivery regimen of claim 140,  
5 wherein the nitrogen mustard derivative is thiotepa.

149. The drug delivery regimen of claim 140,  
wherein the adjuvant biological response modifier is  
selected from the group consisting of alpha-interferon,  
10 TNF (tumor necrosis factor), EPO (erythropoietin), rhG-  
CSF (recombinant human granulocyte colony-stimulating  
factor), IL-1 (interleukin-1), IL-2 (interleukin-2),  
monoclonal antibodies to tumor and immunologic targets  
and combinations thereof.

15  
150. The drug delivery regimen of claim 122,  
wherein the inhaled steroid is selected from the group  
consisting of beclomethasone dipropionate, budesonide,  
flunisolide, fluticasone propionate, mometasone furoate,  
20 triamcinolone acetonide and combinations thereof.

151. The drug delivery regimen of claim 122,  
wherein the lipid lowering agent is selected from the

group consisting of nicotinic acid, HMG CoA reductase inhibitors, bile sequestration agents, fibric acid derivatives and combinations thereof.

5           152.   The drug delivery regimen of claim 151, wherein the HMG CoA reductase inhibitor is selected from the group consisting of atorvastatin, cerivastatin, fluvastatin, lovastatin, pravastatin, simvastatin and combinations thereof.

10

153.   The drug delivery regimen of claim 151, wherein the bile sequestration agent is selected from the group consisting of colestipol, cholestyramine and combinations thereof.

15

154.   The drug delivery regimen of claim 151, wherein the fibric acid derivative is selected from the group consisting of clofibrate, gemfibrozil and combinations thereof.

20

155.   The drug delivery regimen of claim 122, wherein the thrombolytic, anticoagulant, fibrinolytic agent is selected from the group consisting of heparin-

like agents, clot buster agents, aspirin-like agents, platelet glycoprotein IIb, IIIa receptor antagonists and combinations thereof.

5           156.   The drug delivery regimen of claim 154, wherein the heparin-like agent is selected from the group consisting of enoxaparin, dalteparin, refludan and combinations thereof.

10           157.   The drug delivery regimen of claim 154, wherein the clot buster agent is selected from the group consisting of streptokinases, alteplase (TPA) and combinations thereof.

15           158.   The drug delivery regimen of claim 155, wherein the aspirin-like agent is a thromboxane inhibitor.

20           159.   The drug delivery regimen of claim 155, wherein the platelet glycoprotein IIb, IIIa receptor antagonist is selected from the group consisting of tirofiban, eptifibatide, abciximab and combinations thereof.

160. The drug delivery regimen of claim 122,  
wherein the vitamin(s) is selected from the group  
consisting of thiamine, niacinamide, pyridoxine, ascorbic  
acid, riboflavin, folic acid, vitamin A, vitamin E,  
5 vitamin D3, cyanocobalamin, biotin, pantothenic acid,  
derivatives thereof, and combinations thereof.

161. The drug delivery regimen of claim 122,  
wherein the herbal agent(s) is selected from the group  
10 consisting of black cohosh, licorice, false unicorn,  
siberian ginseng, sarsaparilla, squaw vine, blessed  
thistle, peppermint, spearmint, red raspberry, St.  
Johnswort, ginger, kola, hops, valerian, derivatives  
thereof and combinations thereof.

15 162. The drug delivery regimen of claim 122,  
wherein the fatty acid(s) is selected from the group  
consisting of linoleic acid, linolenic acid,  
docosahexaenoic acid, arachidonic acid, eicosahexanoic  
20 acid, omega-3 fatty acid, omega-2 fatty acid, derivatives  
thereof and combinations thereof.

163. The drug delivery regimen of claim 122, wherein the mineral(s) is selected from the group consisting of copper, zinc, iodide, magnesium, chromium, molybdenum, sodium, calcium, iron, fluoride, phosphorus, manganese, potassium, boron, selenium, bioflavonoid, phosphate, derivatives thereof and combinations thereof.

164. The drug delivery regimen of claim 122, wherein the electrolyte(s) is selected from the group consisting of potassium, magnesium, sodium, calcium, derivatives thereof or combinations thereof.

165. A method of enhancing the therapeutic effect of an active therapeutic substance(s) selected from the group consisting of an anti-hypertensive agent, an osteoporotic agent, a GERD agent, an anti-viral agent, an anti-neoplastic agent, an inhaled steroid, a lipid lowering agent, a thrombolytic agent, an anticoagulant agent, a fibrinolytic agent, a hormone agent, an anti-arthritic agent, an antibiotic agent, an analgesic agent, a central nervous system agent, a psychotropic agent, a vitamin, an herbal agent, a fatty acid, a mineral, an

electrolyte and combinations thereof in an animal, which comprises:

- (a) determining known pharmacokinetic parameters of the active therapeutic substance(s);
- 5 (b) determining a number of doses to be administered during a 24 hour period of time and determining a time at which each dose will be administered by considering both the animal's schedule and physiological anomalies during the 24 hour period; and
- 10 (c) independently calculating the amount of each dose in accordance with the equation
$$TD(t) = CD(t) + RD(t)$$
where t is the time at which the dose is to be administered, TD (therapeutic dose) is the therapeutically effective dose at time (t), CD (current dose) is the dose to be administered at time (t), RD (residual dose) is the amount of active therapeutic substance(s) remaining from the previous dose administration.

15 166. The method of claim 165, wherein the anti-hypertensive agent is selected from the group consisting

20

of a calcium channel blocker, an ACE inhibitor, an  
angiotensin II receptor antagonist, a beta-adrenoceptor  
antagonist, an alpha 1-adrenoceptor antagonists, an alpha  
2-adrenoceptor antagonist, a diuretic and combinations  
5 thereof.

167. The method of claim 166, wherein the calcium  
channel blocker is nifedipine, verapamil, nicardipine,  
diltiazem, isradipine, amlodipine, felodipine,  
10 nifedipine, bepridil or combinations thereof.

168. The method of claim 166, wherein the ACE  
inhibitor is quinapril, ramipril, captopril, benazepril,  
fosinopril, lisinopril, moexipril, enalapril or  
15 combinations thereof.

169. The method of claim 166, wherein the  
angiotensin II receptor antagonist is losartan.

20 170. The method of claim 166, wherein the beta  
adrenoceptor antagonist is sotalol, timolol, esmolol,  
carteolol, propanolol, betaxolol, penbutolol, metoprolol,

labetalol, acebutolol, atenolol, bisoprolol or combinations thereof.

5 171. The method of claim 166, wherein the alpha 1-adrenoceptor antagonist is doxazosin, phenoxybenzamine, guanethidine, guanadrel, terazosin, prazosin or combinations thereof.

10 172. The method of claim 166, wherein the alpha 2-adrenoceptor agonist is methyldopa, clonidine, guanfacine or combinations thereof.

15 173. The method of claim 166, wherein the diuretic is selected from the group consisting of carbonic anhydrase inhibitors, loop diuretics, thiazides, potassium sparing diuretics or combinations thereof.

20 174. The method of claim 165, wherein the osteoporotic agent is alendronate, etidronate, pamidronate, clodronate, tiludronate, residronate, ibandronate or combinations thereof.

175. The method of claim 165, wherein the GERD agent is selected from the group consisting of oral GI prokinetic agents, agents active against *H. Pylori*, proton pump inhibitors,  $H_2$  histamine receptor antagonists, antacids and combinations thereof.

176. The method of claim 175, wherein the oral GI prokinetic agent is cisapride monohydrate, metoclopramide or combinations thereof.

177. The method of claim 175, wherein the agent active against *H. Pylori* is clarithromycin, tetracycline, amoxicillin, bismuth, metronidazole or combinations thereof.

178. The method of claim 175, wherein the proton pump inhibitor is selected from the group consisting of omeprazole, lansoprazole and combinations thereof.

179. The method of claim 175, wherein the  $H_2$  histamine receptor antagonist is cimetadine, famotidine, nizatidine, ranitidine, roxatidine and combinations thereof.

180. The method of claim 175, wherein the anti-viral agent is selected from the group consisting of nucleoside analogs, protease inhibitors and combinations thereof.

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181. The method of claim 180, wherein the nucleoside analog is zidovudine, azidothymidine, didanosine, zalcitabine, stavudine, lamivudine or combinations thereof.

10

182. The method of claim 180, wherein the protease inhibitor is selected from the group consisting of saquinavir mesylate, ritonavir, indinavir and combinations thereof.

15

183. The method of claim 165, wherein the anti-neoplastic agent is selected from the group consisting of cytotoxic agents, anti-metabolites, platinum-containing compounds, antibiotic derivatives, fluoropyrimidines, nitrosoureas, vinca alkaloids, nitrogen mustard derivatives, adjuvant biological response modifiers and combinations thereof.

20

184. The method of claim 183, wherein the cytotoxic agent is selected from the group consisting of placlitaxel, cyclophosphamide, teniposide and combinations thereof.

5

185. The method of claim 183, wherein the anti-metabolite is methotrexate.

10

186. The method of claim 183, wherein the platinum-containing compound is selected from the group consisting of cisplatin (cis-diaminedichlororoplatinum), carboplatin, oxaliplatin and combinations thereof.

15

187. The method of claim 183, wherein the antibiotic derivative is adriamycin, bleomycin, dactinomycin, daunorubicin, doxorubicin, indarubicin, mytomyacin or combinations thereof.

20

188. The method of claim 183, wherein the fluoropyrimidine is 5-FU (5-fluorouracil), FudR (5-fluoro-2'-deoxyuridine), Ara-C (arabinosylcytosine) or combinations thereof.

Atty. Docket No. 23233-YX

189. The method of claim 183, wherein the nitrosourea is BCNU (carmustine), streptozocin or combinations thereof.

5 190. The method of claim 183, wherein the vinca alkaloid is vinblastine, vincristine or combinations thereof.

10 191. The method of claim 183, wherein the nitrogen mustard derivative is thiotepa.

15 192. The method of claim 183, wherein the adjuvant biological response modifier is selected from the group consisting of alpha-interferon, TNF (tumor necrosis factor), EPO (erythropoietin), rhG-CSF (recombinant human granulocyte colony-stimulating factor), IL-1 (interleukin-1), IL-2 (interleukin-2), monoclonal antibodies to tumor and immunologic targets and combinations thereof.

20

193. The method of claim 165, wherein the inhaled steroid is beclomethasone dipropionate, budesonide,

flunisolide, fluticasone propionate, mometasone furoate, triamcinolone acetonide or combinations thereof.

194. The method of claim 165, wherein the lipid  
5 lowering agent is selected from the group consisting of nicotinic acid, HMG CoA reductase inhibitors, bile sequestration agents, fibric acid derivatives and combinations thereof.

10 195. The method of claim 194, wherein the HMG CoA reductase inhibitor is atorvastatin, cerivastatin, fluvastatin, lovastatin, pravastatin, simvastatin or combinations thereof.

15 196. The method of claim 194, wherein the bile sequestration agent is colestipol, cholestyramine or combinations thereof.

20 197. The method of claim 194, wherein the fibric acid derivative is clofibrate, gemfibrozil or combinations thereof.

198. The method of claim 165, wherein the thrombolytic, anticoagulant, fibrinolytic agent is selected from the group consisting of heparin-like agents, clot buster agents, aspirin-like agents, platelet glycoprotein IIb, IIIa receptor antagonists and combinations thereof.

199. The method of claim 198, wherein the heparin-like agent is enoxaparin, dalteparin, refludan or combinations thereof.

200. The method of claim 198, wherein the clot buster agent is selected from the group consisting of streptokinases, alteplase (TPA) and combinations thereof.

201. The method of claim 198, wherein the aspirin-like agent is a thromboxane inhibitor.

202. The method of claim 198, wherein the platelet glycoprotein IIb, IIIa receptor antagonist is tirofiban, eptifibatide, abciximab or combinations thereof.

203. The method of claim 165, wherein the vitamin  
is thiamine, niacinamide, pyridoxine, ascorbic acid,  
riboflavin, folic acid, vitamin A, vitamin E, vitamin D3,  
cyanocobalamin, biotin, pantothenic acid, derivatives  
thereof or combinations thereof.

204. The method of claim 165, wherein the herbal  
agent is black cohosh, licorice, false unicorn, siberian  
ginseng, sarsaparilla, squaw vine, blessed thistle,  
peppermint, spearmint, red raspberry, St. Johnswort,  
ginger, kola, hops, valerian, derivatives thereof or  
combinations thereof.

205. The method of claim 165, wherein the fatty  
acid is selected from the group consisting of linoleic  
acid, linolenic acid, docosahexaenoic acid, arachidonic  
acid, eicosahexanoic acid, omega-3 fatty acid, omega-2  
fatty acid, derivatives thereof and combinations thereof.

206. The method of claim 165, wherein the mineral  
is selected from the group consisting of copper, zinc,  
iodide, magnesium, chromium, molybdenum, sodium, calcium,  
iron, fluoride, phosphorus, manganese, potassium, boron,

selenium, bioflavonoid, phosphate, derivatives thereof and combinations thereof.

207. The method of claim 165, wherein the electrolyte is selected from the group consisting of potassium, magnesium, sodium, calcium, derivatives thereof and combinations thereof.

208. The method of claim 165, wherein the active therapeutic substance(s) is administered at least twice and may be administered as immediate release, sustained release, controlled release, delayed release, timed release, extended release or any combination thereof.

209. The method of claim 165, wherein the active therapeutic substance(s) is administered by pulsatile delivery of the active therapeutic substance(s).

210. The method of claim 165, wherein the active therapeutic substance(s) is administered in a dosage form independently selected from the group consisting of Examples of such dosage forms include, without limitation, chewable tablets, quick dissolve tablets,

effervescent tablets, reconstitutable powders, elixirs,  
liquids, solutions, suspensions, emulsions, tablets,  
multi-layer tablets, bi-layer tablets, capsules, soft  
gelatin capsules, hard gelatin capsules, caplets,  
5 lozenges, chewable lozenges, beads, powders, granules,  
particles, microparticles, dispersible granules, cachets,  
douches, suppositories, creams, topicals, inhalants,  
aerosol inhalants, patches, particle inhalants, implants,  
depot implants, ingestibles, injectables, infusions,  
10 health bars, confections, animal feeds, cereals, cereal  
coatings, foods, nutritive foods, functional foods, by a  
vaporizer and combinations thereof.

211. The method of claim 165, wherein the active  
15 therapeutic substance(s) is administered in a dosage form  
independently selected from the group consisting of a  
tablet, multi-layer tablet, capsule and caplet.

212. The method of claim 165, wherein the active  
20 therapeutic substance(s) is administered in uneven doses.

213. The method of claim 165, wherein the active therapeutic substance(s) is administered at uneven time intervals over the course of the 24 hour period.

5           214. The method of claim 165, wherein an AM dose and a PM dose are administered, and wherein the AM dose is larger or smaller than the PM dose.

10           215. The method of claim 165, wherein an AM dose and a PM dose are administered, and wherein the AM dose has a higher or lower amount of a water-soluble active therapeutic substance(s) present than that present in the PM dose.

15           216. The method of claim 165, wherein an AM dose and a PM dose are administered, and wherein the AM dosage has a higher or lower amount of a non water-soluble drug present than that present in the PM dosage.

20           217. The method of claim 165, wherein the dosage is adjusted for subsequent 24 hour periods of time.

218. The method of claim 165, wherein the active therapeutic substance(s) is substituted for another active therapeutic substance(s).

5 219. The method of claim 165, wherein two PM doses are administered, and wherein the first PM dose is administered immediately after dinner and the second PM dose is administered immediately prior to bedtime.

10 220. A method for maximizing therapeutic effectiveness of an antihypertensive agent, which comprises:

administering a first dose of the antihypertensive agent at a first preselected time during a twenty four  
15 hour period;

administering a second dose of the antihypertensive agent at a second preselected time during the twenty four hour period;

20 wherein said first dose is about 30% of the total amount of the antihypertensive agent to be administered during the twenty four hour period and the second dose is about 70% of the total amount of the antihypertensive

agent to be administered during the twenty four hour period;

and wherein said first preselected time is about 6-8 am and the second preselected time is about 6-8 pm.

5

221. The method of claim 220, wherein the anti-hypertensive agent is selected from the group consisting of a calcium channel blocker, an ACE inhibitor, an angiotensin II receptor antagonist, a beta-adrenoceptor antagonist, an alpha 1-adrenoceptor antagonists, an alpha 2-adrenoceptor antagonist, a diuretic and combinations thereof.

222. The method of claim 221, wherein the calcium channel blocker is selected from the group consisting of nifedipine, verapamil, nicardipine, diltiazem, isradipine, amlodipine, felodipine, nifedipine, bepridil and combinations thereof.

223. The method of claim 221, wherein the ACE inhibitor is selected from the group consisting of quinapril, ramipril, captopril, benazepril, fosinopril,

lisinopril, moexipril, enalapril and combinations thereof.

224. The method of claim 221, wherein the  
5 angiotensin II receptor antagonist is losartan.

225. The method of claim 221, wherein the beta  
adrenoceptor antagonist is selected from the group  
consisting of sotalol, timolol, esmolol, carteolol,  
10 propanolol, betaxolol, penbutolol, metoprolol, labetalol,  
acebutolol, atenolol, bisoprolol and combinations  
thereof.

226. The method of claim 221, wherein the alpha 1-  
15 adrenoceptor antagonist is selected from the group  
consisting of doxazosin, phenoxybenzamine, guanethidine,  
guanadrel, terazosin, prazosin and combinations thereof.

227. The method of claim 221, wherein the alpha 2-  
20 adrenoceptor agonist is selected from the group  
consisting of methyldopa, clonidine, guanfacine and  
combinations thereof.

228. The method of claim 221, wherein the diuretic is selected from the group consisting of carbonic anhydrase inhibitors, loop diuretics, thiazides, potassium sparing diuretics and combinations thereof.

5

229. A method for maximizing therapeutic effectiveness of an osteoporotic agent, which comprises:

administering a first dose of the osteoporotic agent at a first preselected time during a twenty four hour period of time to an animal;

10

administering a second dose of the osteoporotic agent at a second preselected time during the twenty four hour period of time to the animal;

15

wherein said first dose is about 25% to about 35% of the total amount of the osteoporotic agent to be administered during the twenty four hour period of time and the second dose is about 65% to about 75% of the total amount of the osteoporotic agent to be administered during the twenty four hour period of time;

20

and wherein said first preselected time is the period between the animal's awakening until just after the animal's morning meal and the second preselected time

is the period between the animal's evening meal and the animal's bedtime.

230. The method of claim 229, wherein the  
5 osteoporotic agent is selected from the group consisting of alendronate, etidronate, pamidronate, clodronate, tiludronate, residronate, ibandronate and combinations thereof.

10 231. A method for maximizing therapeutic effectiveness of AZT, which comprises:

administering a first dose of AZT at a first  
preselected time during a twenty four hour period of time  
to an animal;

15 administering a second dose of AZT at a second  
preselected time during the twenty four hour period of  
time to the animal;

administering a third dose of AZT at a third  
preselected time during the twenty four hour period of  
20 time to the animal;

wherein said first dose and the third dose are equal  
and at least 70% of the second dose;

and wherein said first preselected time is from 6 am to 9 am, the second preselected time is from 3 pm to 6 pm and the third preselected time is from 9 pm to 12 pm.

5           232. A pharmaceutical composition for optimizing therapeutic activity, which comprises:

          a first active therapeutic substance(s) selected from the group consisting of water-soluble vitamins, water -soluble minerals and water-soluble electrolytes;  
10           and

          a second active therapeutic substance(s) selected from the group consisting of non water-soluble vitamins, non water-soluble minerals and fatty acids;

          wherein the ratio of the first active therapeutic  
15           substance(s) to the second active therapeutic substance(s) is independently tailored to optimize levels of the respective active therapeutic substances at a site or sites of action in an animal for maximum efficacy, and wherein said weight ratio is determined according to the  
20           time at which said composition is to be administered with a suitable pharmaceutical carrier.

233. The pharmaceutical composition of claim 232, wherein the water-soluble vitamin is selected from the group consisting of vitamin B<sub>1</sub>, vitamin B<sub>2</sub>, vitamin B<sub>3</sub>, biotin, pantothenic acid, vitamin B<sub>6</sub>, folate, vitamin B<sub>12</sub>,  
5 vitamin C, derivatives thereof and combinations thereof.

234. The pharmaceutical composition of claim 232, wherein the water-soluble mineral is selected from the group consisting of sodium, potassium, calcium,  
10 phosphorus, magnesium, sulfur, ferrous iron, zinc, iodide, copper, fluoride, derivatives thereof and combinations thereof.

235. The pharmaceutical composition of claim 232, wherein the water-soluble electrolyte is selected from  
15 the group consisting of sodium, potassium, calcium, magnesium, derivatives thereof and combinations thereof.

236. The pharmaceutical composition of claim 232, wherein the non water-soluble vitamin is selected from  
20 the group consisting of vitamin A, vitamin D, vitamin E, vitamin K, derivatives thereof and combinations thereof.

237. The pharmaceutical composition of claim 232,  
wherein the non water-soluble mineral is selected from  
the group consisting of chromium, ferric iron,  
molybdenum, selenium, derivatives thereof and  
5 combinations thereof.

238. The pharmaceutical composition of claim 232,  
wherein the fatty acid is selected from the group  
consisting of linoleic acid, linolenic acid, arachidonic  
10 acid, eicopentaenoic acid, docosahexaenoic acid, omega-2  
fatty acid, omega-3 fatty acid, derivatives thereof and  
combinations thereof.